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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,559	06/18/2001	Michael Kramer	4007-001	3025

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AKERMAN SENTERFITT
P.O. BOX 3188
WEST PALM BEACH, FL 33402-3188

EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	
MAIL DATE	**DELIVERY MODE**
11/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/787,559	KRAMER ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,8-10,17,29 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,8-10 and 29* is/are rejected.

7)☒ Claim(s) *17 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *attached* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/15/2007 has been entered.

Claims 2, 3, 8-10, 17, 29 and 30 are currently pending in the application and are addressed herein.

Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention.

Claim 2 recites, "An isolated nucleic acid **comprising a nucleotide sequence selected from** the group consisting of..." (Emphasis Added). Given the broadest reasonable interpretation, the phrase "a nucleotide sequence selected from the group consisting of" can be

interpreted as encompassing any nucleotide sequence that is selected from the group of nucleotide sequences indicated in (i)-(iv), including any nucleotide sequence that is a fragment of any sequence indicated in (i)-(iv). In other words, since "a nucleotide sequence" is properly interpreted as "any nucleotide sequence" the claims encompass any nucleotide sequence taken from the group consisting of (v)-(iv), including any partial nucleotide sequence, such as a fragment of any one of (i)-(iv). Therefore, the claims encompass any nucleotide sequence that has at least two consecutive nucleotides of SEQ ID No. 1 or SEQ ID No. 4 or their antisense strands. Random hexanucleotides were available for sale as early as 1997 (see 1997 Boehringer Mannheim Catalog, page 95, previously of record). The hexanucleotide mix available comprised, "mixture of hexamer nucleotides of all possible sequences for random primed DNA labeling." Therefore, there existed within the hexanucleotide mix at least one nucleotide sequence that has at least two consecutive nucleotides of SEQ ID No. 1 or SEQ ID No. 4 or their antisense strands. Claim 3 encompasses the nucleotide sequence of claim 2; therefore, they are rejected for the same reason.

3. Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Mierendorf et al. (U.S. patent 5,629,179; previously of record).

Mierendorf et al. teaches a method and kit for making a cDNA library wherein the kit comprises random octamer oligonucleotides over every possible sequence (see column 7, line 59-column 8, line 6). As mentioned above, Claim 2 recites, "An isolated nucleic acid **comprising a nucleotide sequence selected from** the group consisting of..." (Emphasis Added), and encompass any nucleotide sequence that has at least two consecutive nucleotides of

SEQ ID No. 1 or SEQ ID No. 4 or their antisense strands. Mierendorf et al. teaches a kit comprising every possible octamer oligonucleotide. Therefore, the kit taught by Mierendorf et al. includes 8mer (i.e. octamer) oligonucleotides which have at least two consecutive nucleotides of SEQ ID No. 1 or SEQ ID No. 4 or their antisense strands.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 8-10, 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. The instant claims are drawn to a recombinant DNA vector molecule which comprises a nucleic acid according to claim 2 wherein said DNA vector molecule expresses protein pKe#122 in a prokaryotic or eukaryotic cell. It is noted that the claim does not limit protein pKe#122 to any specific sequence. It is also pointed out that the specification specifically describes the pKe#122 protein as follows:

> Protein pKe#122 and the polypeptides related thereto, i.e., to the amino acid sequence indicated in the SEQ ID NO:2 sequence protocol or SEQ ID NO:3 sequence protocol, specifically the polypeptides that can be derived through substitution, deletion, insertion and/or inversion from one of these amino acid sequences according to SEQ ID NO:2 or SEQ ID NO:3, or that have an amino acid sequence resulting from a splice variant of an mRNA, which is identical or complementary to the nucleotide

> sequence indicated in the SEQ ID NO:I sequence protocol or the SEQ ID NO:4 sequence protocol, or to a partial sequence of these nucleotide sequences, or at least hybridized, offer numerous applications in the area of dermatological research and development.

Furthermore, as indicated above, claim 2 encompasses any nucleic acid sequence, including any fragment of SEQ ID NO: 1, SEQ ID NO: 4, antisense strands thereof, etc. Therefore, the instant claims encompass an enormous number of different nucleic acid sequences that can encode pKe#122 protein given the broad description of "pKe#122 protein" is intended to encompass, as indicated in the specification. However, the specification has only disclosed the protein named pKe#122, which is encoded by SEQ ID No. 1 or SEQ ID No. 4. Thus, applicant has express possession of only two species (SEQ ID No. 1 and SEQ ID No. 4) in a genus which comprises possibly hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

> It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the sequences of the disclosed SEQ ID Nos. are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention

being, for purposes of "written description" inquiry, whatever is presently claimed."

Claim Objections

7. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 is drawn to the isolated nucleic acid of claim 2 wherein the nucleic acid is obtained by natural, synthetic or semi-synthetic source. This fails to limit claim 2 because there is no other possible source from which the nucleic acid could be obtained.

8. Claims 17 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Miscellaneous

Applicants are asked to review the oath/declaration of the instant application which lists the inventors as Kramer, Bechtel, Reinartz, Schaefer and Wallich and compare this to those listed as the inventors of PCT/DE99/02865 (published as WO 00017232) which appears to be Bechtel, Reinartz, Schaefer and Wallich. It is noted that the instant case is the national stage filing (i.e., 371 filing) of the indicated PCT and it is unclear why Kramer is now listed as an inventor but was not previously identified as such in the PCT. Applicants should clarify the correct inventors and take the appropriate steps to correct the discrepancy.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner
Art Unit 1635